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OPPEDAHL AND LARSON LLP
P O BOX 5068
DILLON, CO 80435-5068

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HELMS, LARRY RONALD	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040304

Application Number: 08/940,544
Filing Date: September 30, 1997
Appellant(s): SADELAIN ET AL.

Ms. Larson Ph.D
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/5/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The Brief includes a statement of the grouping of the claims.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,686,281	Roberts	11-1997

WO 93/19163 Eshhar et al, published 9-1993

Sambrook et al., Molecular Cloning, a Laboratory Manual, second ED, Cold Spring Harbor Laboratory Press, page 16.9 and 16.11, 1989.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Eshhar et al (WO 93/19163, published 9/30/93).

a. The claims recite a recombinant polynucleotide encoding a fusion protein comprising a single chain antibody and a signaling domain of human CD28 receptor and a transmembrane domain of human CD28 between the single-chain antibody and the signaling domain.

b. Eshhar et al teach a polynucleotide encoding a fusion protein comprising a single chain antibody and the transmembrane and cytoplasmic domain of CD28 (see page 7 and 8 and pages 18-19).

Appellant's argue on page 4-5 of the Brief that Eshhar fails to actually teach a CD28 containing fusion protein or the nucleotide encoding it. In response to this argument, Eshhar clearly teach polynucleotides encoding single-chain domains fused to extracellular and transmembrane domains of lymphocyte-activation molecules (see page 8, lines 9-16) of which CD28 is among the members of lymphokine receptors (see page 8, lines 35-36). To the extent that Eshhar specifically describes a polynucleotide that may contain the fusion components which is within the claims on appeal, it does not matter for the purpose of finding anticipation that Eshhar actually made such a

composition, i.e., actually reduced that composition to practice, or only describes such a composition as part of his invention. In re Sivaramakrishnan , 673 F.2d 1383, 213 USPQ.

Appellant's argue on page 5-6 of the Brief that Eshhar does not provide an enabling disclosure and does not teach the sequence of CD28 or primers for extracting CD28. In response to this argument, Eshhar teaches several molecules and their invention is fusion proteins made by recombinant DNA methods and as such the prior art does not have to teach what is previously known and because Eshhar states the molecule can be CD28, it teaches CD28. Appellant's are also directed to MPEP 2131.02 which states "when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that "the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication."). Id. at 1718. See also In re Sivaramakrishnan, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982).

Appellant's argue on page 6-9 of the Brief that Eshhar does not provide a written description of CD28 because there is no sequence of the protein or polynucleotide of

CD28. In response to this argument, the above response to the enablement issue is restated and Appellant's are directed to MPEP 2131.02.

B. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Roberts (U.S. Patent 5,686,281, filed 5/1995, IDS #24)

The claims recite a recombinant polynucleotide encoding a single-chain antibody, a signaling domain of human CD28 receptor and a human CD28 transmembrane domain disposed between the single-chain and the signaling domain.

Roberts teach polynucleotides that encode human CD28 cytoplasmic and transmembrane domains fused to a single-chain antibody (see column 6, lines 55-67).

Appellant's argue on page 9 of the brief that Roberts fails to provide a disclosure that anticipates claims 1 and 2 for the same reasons as Eshhar does. Appellant's state that the patent asserts that essentially anything with binding function can serve as the extracellular domain and mentions scFv and does not have any examples of scFv containing fusions nor any specific teachings of how to make such. In response to this argument, the same response as above to the Eshhar arguments are stated. Appellant's are also directed to MPEP 2131.02 which states "when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate

the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that "the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication."). Id. at 1718. See also In re Sivaramakrishnan, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982).

C. Claims 1-2, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eshhar et al (WO 93/19163, published 9/30/93) as applied to claims 1-2 above and further in view Sambrook et al (Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory, 1989).

The claims are drawn to a recombinant polynucleotide encoding a fusion protein comprising the variable region of the light chain linked to the variable region of the heavy chain of a single chain antibody, signal domain of human CD28 receptor and a human transmembrane domain, further comprising a suicide gene encoding thymidine kinase.

Eshhar et al teach polynucleotides encoding CD28 fusions with a single chain antibody. Eshhar et al does not teach a polynucleotide further comprising a gene encoding thymidine kinase. This deficiency is made up for in the teachings of Sambrook et al.

Sambrook et al teach the thymidine kinase gene, which is expressed in most mammalian cells (Page 16.9). Sambrook et al also teach a plasmid, pTK2, which carries a fragment of the herpes simplex virus (HSV) encoding thymidine kinase (tk) (see page 16.11, Figure 16.1A).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a polynucleotide encoding a fusion protein comprising a single chain antibody and a signaling domain of human CD28 and human CD28 transmembrane domain and a gene coding for thymidine kinase.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to produce a polynucleotide encoding a fusion protein comprising a single chain antibody and a signaling domain of human CD28 and human CD28 transmembrane domain and a gene coding for thymidine kinase because Sambrook et al teach a medium containing hypoxanthine, aminopterin, and thymidine (HAT medium) "in which only cells expressing the tk gene will grow. Thus, by using the appropriate medium it is therefore possible to select for cells expressing the tk gene". Thus, it would have been obvious to combine the teaching of Eshhar et al for producing a polynucleotide encoding for a fusion protein of a single chain antibody and the signaling and transmembrane domains of CD28 and further combine this polynucleotide with a polynucleotide encoding the thymidine kinase protein of Sambrook et al for selection of cells expressing the polypeptide.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art a the time the invention was made, as evidenced by the references.

Appellant's argue this rejection with the 103 with Roberts. Appellant's argue on page 9-10 of the Brief that the primary references are inappropriately relied on for anticipation and the secondary reference does not overcome the difficulties of Eshhar and Roberts reference with regard to enablement and written description. In response to this argument, with regard to enablement and written description for Eshhar and Roberts, this was addressed above in the 102 rejections. The art of Sambrook, or the secondary reference, provides motivation for a polynucleotide with a gene encoding thymidine kinase for selection of the expressing polypeptide.

D. Claims 1-2, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts (U.S. Patent 5,686,281, filed 5/1995, IDS #24) as applied to claims 1-2 above and further in view Sambrook et al (Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory, 1989).

The claims have been described supra.

Roberts teach polynucleotides that encode human CD28 cytoplasmic and transmembrane domains fused to a single-chain antibody (see column 6, lines 55-67). Roberts does not teach a polynucleotide further comprising a gene encoding thymidine kinase. This deficiency is made up for in the teachings of Sambrook et al.

Sambrook et al has been described supra.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a polynucleotide encoding a fusion

protein comprising a single chain antibody and a signaling domain of human CD28 and human CD28 transmembrane domain and a gene coding for thymidine kinase.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to produce a polynucleotide encoding a fusion protein comprising a single chain antibody and a signaling domain of human CD28 and human CD28 transmembrane domain and a gene coding for thymidine kinase because Sambrook et al teach a medium containing hypoxanthine, aminopterin, and thymidine (HAT medium) "in which only cells expressing the tk gene will grow. Thus, by using the appropriate medium it is therefore possible to select for cells expressing the tk gene". Thus, it would have been obvious to combine the teaching of Roberts et al for producing a polynucleotide encoding for a fusion protein of a single chain antibody and the signaling and transmembrane domains of CD28 and further combine this polynucleotide with a polynucleotide encoding the thymidine kinase protein of Sambrook et al for selection of cells expressing the polypeptide.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art a the time the invention was made, as evidenced by the references.

Appellant's argue this rejection with the 103 with Eshhar. Appellant's argue on page 9-10 of the Brief that the primary references are inappropriately relied on for anticipation and the secondary reference does not overcome the difficulties of Eshhar and Roberts reference with regard to enablement and written description. In response to this argument, with regard to enablement and written description for Eshhar and Roberts, this was addressed above in the 102 rejections. The art of Sambrook, or the

secondary reference, provides motivation for a polynucleotide with a gene encoding thymidine kinase for selection of the expressing polypeptide.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Larry R. Helms
March 8, 2004

Conferees

Yvonne EylerSPE 1642

Gary Kunz SPE 1647

OPPEDAHL AND LARSON LLP
P O BOX 5068
DILLON, CO 80435-5068

LARRY R. HELMS, PH.D
PRIMARY EXAMINER

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600